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EXAMINER	
MCEVOY, THOMAS M	

ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,825	WEBER ET AL.	
	Examiner	Art Unit	
	THOMAS MCEVOY	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-28,30-38,43,50-59,61-63,65,66,69-76 and 78-87* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,9-13,15,16,24,25,28,30-32,34-38,50,52,54,56,57,61,63,71-74 and 80-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 7,8,14,17-23,26,27,33,43,51,53,55,58,59,62,65,66,69,70,75,76,78 and 79.

DETAILED ACTION

1. Currently claims 1-28, 30-38, 43, 50-63, 65, 66, 69-76 and 78-87 are pending. Claims 7, 8, 14, 17-23, 26, 27, 33, 43, 51, 53, 55, 58, 59, 62, 65, 66, 69, 70, 75, 76, 78 and 79 have been withdrawn. Claims 5, 29, 39-42, 44-49, 60, 64, 67, 68 and 77 have been cancelled. Claims 1-4, 6, 9-13, 15, 16, 24, 25, 28, 30-32, 34-38, 50, 52, 54, 56, 57, 61, 63, 71-74 and 80-87 are considered below.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 4th 2008 has been entered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Examiner can not any disclosure for Applicant's elected species that incorporates both a circumferential band and a longitudinal strip in the active region.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 52, 54, 56, 57, 61 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the limitation "The medical device" in line 1. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-4, 6, 9-11, 12, 13, 15, 16, 24, 25, 28, 30-32, 34-38, 50, 52, 54, 56, 57, 61, 63, 71-74 and 80-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maseda (US 6,514,237) in view of Couvillon (US 2003/0236531).

Regarding claims 1, 4, 6, 12, 13, 15, 16, 28, 36, 37, 50, 52, 54, 56, 57, 61, 71, 72 and 84, Maseda discloses a medical catheter comprising (a) an elongate body 114 adapted for insertion into a body lumen, said elongate body having distal and proximal ends and an axis; (b) a balloon 118; and (c) an active region (magnified secion, Figure 5) comprising a conductive polymer 500 disposed over the elongate body. Maseda fails

to specifically disclose other types of electroactive polymers, such as those which are actuated by volumetric expansion, but clearly indicates that the electroactive polymer used in his disclosure is for explanatory purposes only. Couvillon discloses the device as previously made of record where the electroactive polymer strands expand the end of the device in much the same way as a balloon (Figures 2, 7 and 8) which can overcome the stress exerted by smooth muscle cells (paragraph 0039). Couvillon discloses that the electroactive polymer strips can expand a balloon-like structure (Figure 2B) in a continuous band (except for being interrupted by aperture 103 (Figures 2A-B). Maseda discloses that the electroactive polymer strands may be incorporated into various segments (or any segment) of the device so that the device expands like and mimics a balloon in a balloon catheter (col. 3, lines 3- 6); the circumferential band of composite strands expands and functions like a balloon (col. 6, lines 47-59); and the balloon itself may incorporate the composite strands (col. 8, lines 6-9). It would have been obvious to one of ordinary skill in the art in view of Couvillon that the Maseda device could be expanded by volumetrically expanding electroactive polymers because they would be effective at overcoming the stress of smooth muscle that lines vessel walls when dilating a vessel or maneuvering the catheter within a vessel. It would have been obvious to one of ordinary skill in the art, in view of the teachings of Couvillon and the suggestions of Maseda, to expand the balloon of Maseda using strips in the circumferential configuration of Couvillon (though not interrupted by an aperture). Furthermore, since Maseda discloses that the strands can be contained within recesses of the outer tube 114 (col. 5, line 61), it would also have been obvious to one of ordinary

skill in the art to have attached the strands within recesses of tube 116 in order to expand the balloon; using the same structure shown in Figure 5 for example.

Regarding claims 2 and 3, Maseda as combined with Couvillon would use multiple radially expanding bands to expand the balloon.

Regarding claims 9-11 and 38, as explained above, Couvillon teaches that circumferentially oriented electroactive polymer strips can be placed within or under a balloon-like member to expand it. Maseda discloses using any variety of strip geometries (col. 8, lines 12-17), placed within the outer or inner tubular member (col. 8, lines 4-7; col. 5, lines 56-61; col. 6, lines 56-58). It would have been obvious to one of ordinary skill in the art to have incorporated the electroactive polymer actuator strips beneath, within or within recesses of the balloon of Maseda or the inner tube 116, and to have oriented them longitudinally as disclosed by Maseda, or circumferentially as disclosed by Couvillon.

Regarding claims 24, 25, 73, 74 and 80, if the balloon is expanded by the eletroactive polymer strips of Couvillon as described above, the balloon would be stiffened, in a similar manner as disclosed for Applicant's balloon.

Regarding claims 30-32 and 34, in the modified balloon of Maseda as described above, the active region would be able to radially expand the entire balloon, both proximal and distal portions. The electroactive strips of Couvillon volumetrically expand when actuated.

Regarding claim 35, Maseda discloses that the electroactive polymer strips can be incorporated into the catheter tube and then the entire tube is expanded (col. 7, line

58 to col. 8, line 2). It would have been obvious to one of ordinary skill in the art to have expanded the inner tube 116 in this manner in order to expand the balloon because of the suggestions made by Maseda as explained above. In particular, Maseda suggests incorporating the electroactive polymer strips into the balloon (col. 8, lines 8-9).

Regarding claim 63, the insertable body 114 can be extruded (col. 5, line 61).

Regarding claims 80-83 and 86, in the modified balloon of Maseda in view of Couvillon as described above, the active region would be sealed by the balloon if the active region is installed within, beneath or within a recess of the balloon. The electroactive strips of Couvillon incorporate an electrolyte and a counter electrode (Figure 1).

9. Claim 87 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maseda (US 6,514,237) and Couvillon (US 2003/0236531) in view of Sharrow (US 4,793,359).

Regarding claim 87, Maseda as modified by Couvillon discloses the invention as described above comprising a plurality of active regions, where an active region can be one of the electroactive polymer actuator strips and where it would have been obvious to incorporate the strips within, underneath or within a recess of the balloon or inner tubular member 116. Maseda fails to disclose that a first active region is disposed over a first conductive radio-opaque band and wherein a second active region is disposed over a second conductive radio-opaque band that is positioned distal to said first conductive radio-opaque band. Sharrow teaches that a balloon in a balloon catheter can have two conductive (metal) radio-opaque bands positioned at either end of the interior of the balloon to confirm the dilating length of the balloon (col. 4, lines 4-5). It

would have been obvious to one of ordinary skill in the art to have incorporated two conductive (metal) radio-opaque bands positioned at either end of the interior of the balloon to confirm the dilating length of the balloon.

Response to Arguments

10. Applicant's arguments filed February 4th 2009 with respect to the 35 U.S.C 102(e) rejections over Couvillon are persuasive. Examiner has added Couvillon to support the rejections over Maseda to strengthen the motivation for placing the electroactive strips beneath the balloon and in a circumferential orientation. Applicant has argued that placing the electroactive strips beneath the balloon of Maseda would create a situation where it would be uncertain as to how the balloon should be expanded. Examiner respectfully disagrees. In view of Maseda's suggestion to incorporate the strands into the balloon, Maseda's suggestion that electroactive polymer strands can mimic a balloon and apply varying degrees of occluding pressure and Couvillon's teaching of placing electroactive polymer strips/strands within a balloon-like structure, the skilled artisan would recognize that placing the electroactive polymer strands within or under the balloon would enable the operator vary the occluding pressure in selective regions of the balloon and/or better control the occluding pressure. This would not interfere with the balloon's normal inflation mechanism. The remainder of Applicant's arguments have been addressed in the previous Final Rejection and/or Advisory Action of record.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Mcevoy whose telephone number is (571)270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TM

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
4/27/09